Remarks

This amendment is being filed as part of a Request for Continued Prosecution (RCE) under 37 CFR 1.114. As a Notice of Appeal had properly been filed in response to the Office Action of June 7, 2003, there is currently no outstanding office action in this application. However, to expedite prosecution, the issues raised in the Office Action of June 7, 2002, will be addressed in turn in view of the amendments set out above and other grounds for patentability not related to amendment.

Claim 1 was rejected under 35 USC 112, second paragraph. Examiner Clow suggested that the claim should include language directed to "including an initial step in claim 1 of administering a tracer dose of a radiopharmaceutical, collecting data as to its clearance, and using that to establish the optimally effective dose." This basis of potential rejection has been obviated in part by amendment and is otherwise traversed.

Claim 1 was amended as marked above to include "administering to a patent a trace dose" followed by language relating to the trace dose that finds basis in and better fits with the remainder of claim 1 than does the simple recitation of "a radiopharmaceutical" as suggested by the Examiner.

However, there is no need to add any discussion of "collecting data as to its [the trace dose] clearance," as claim 1 already recites "determining a clearance profile for the radiopharmaceutical or the radiopharmaceutical analog" [the last part of this phrase being modified at this time to read "the" instead of "a" at one location in view of the earlier added language about the "trace dose"]. In a similar manner, there is no need to add language relating to "establish[ing] the optimally effective dose," as the last paragraph of the claim as previously presented already recites "establishing the optimally effective dose" in a more specific manner than that requested generally by the Examiner.

Accordingly, this claim has been amended to clarify use of a tracer dose. No other amendment is needed, and the claim is fully ready for allowance under the conditions of 35 USC 112, second paragraph.

Claims "1-24" (actually pending claims 1, 2, 4-20, and 22-24), 83 and 84 were rejected under 35 USC 102(b) over Wahl et al. (WO 96/34632 A1) and claim 19 was further rejected under 35 USC 102(b) over Order (J. Radiation Oncology Bio. Phys. (1980) vol. 6, pp. 703-310). These grounds of potential rejection are traversed.

Both rejections over these references were made under section 102(b) of the patent statutes, which require a complete anticipation of the invention (not an approximation of the invention). See MPEP 706.02(a) under the section entitled Distinction Between 35 USC 102 and 103: "In other words, for anticipation under 35 USC 102, the reference must teach every aspect of the claimed invention either explicitly or implicitly." [MPEP, eighth edition, revision 1 (February 2003), p. 700-21] No rejection was made over either publication under 35 USC 103 on the basis of obviousness and – indeed – no such rejection should have been made as there is nothing in either cited reference to lead to the invention *as claimed.*

The key – as is often the case – is the actual claim language used. While applicant certainly recognizes that the two cited papers recited *other* techniques used in earlier attempts to optimize the optimum dose of a radiopharmaceutical, they do not disclose "every aspect" of the invention as claimed. The claimed invention – as is true of all claimed inventions – does not encompass the universe as a whole or even the smaller universe of each and every radiopharmaceutical dose optimization technique. Instead, it encompasses a particular style of radiopharmaceutical dose optimization *as specifically recited in the claim language.* Although the Examiner has stated several general aspects that are similar (e.g., the discussion at the top of page 3 of the Office Action relating to clearance profiling), this is not enough to show that the invention as claimed has been disclosed by either of the publications. In fact, it has not. Among other aspects of the *claimed* invention not shown in the Wahl publication, for example, are the operations set out in the last paragraph of claim 1.

Applicant is also concerned that the limitations set out in dependent claims have been ignored. None of the dependent claims are discussed at all in the Office Action of June 7, 2002. Yet each dependent claim adds a limitation that – unless also disclosed in the publication under consideration – provides another reason for overcoming a rejection based on anticipation. For example, the specific mathematical operations of some dependent claims are not discussed at all. Any further office action making an anticipation rejection should fully set out basis in the cited prior art on which the Examiner intends to rely *for each claim limitation* so that applicant can fully consider and address, if necessary, the Examiner's concerns.

Accordingly, in view of the amendments and remarks set out above, it is submitted that this application is now ready for allowance. If the Examiner believes that oral discussion would

advance prosecution of the application, she is invited to call the undersigned at the number indicated below. Otherwise, notice of allowance of the application is respectfully requested.

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Respectfully submitted,
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